ADAP ADVISORY COMMITTEE MEETING
April 17, 2007
Virginia Hospital and Healthcare Association

Members present: Linda Eastham RN FNP, George Kelly, Craig Parrish RPh, Daniel Nixon DO, Peg Tipple MD, Karen Council OSS, Donald Walker, David Wheeler MD, Edward Oldfield MD.

VDH Staff: Diana Jordan RN MS, Steve Bailey LCSW, Faye Bates RN.

Other: Anne Rhodes, Mike Phillips

The meeting was called to order at 10:00 a.m. by Diana Jordan, Director of Health Care Services. New members were introduced. Karen Council OSS is the ADAP Coordinator at the Hampton Health Department, and Peg Tipple MD is the Director of Tuberculosis Control under the Division of Disease Prevention. Diana Jordan announced that Casey Riley, Director of the Division of Disease Prevention resigned and Kathryn Hafford is the Acting Director. The minutes of the October 11, 2006 meeting were read and approved with no amendments.

Steve Bailey gave an update on the State Pharmaceutical Assistance Program (SPAP). He stated that the good news was that the SPAP issued an RFP to administer the coordination of benefits for Medicare Part D. A top applicant has been identified, and the contract should be completed soon. The challenge has been that the General Assembly redirected some of the SPAP funding, resulting in fewer funds than anticipated. SPAP will continue premium coverage for all enrollees. There will be a wait list for the medication benefit, and those clients will remain on ADAP without interruption to their medication. The SPAP will provide medication coverage to clients at one third the cost of maintaining those same clients on ADAP, and the SPAP will provide access to all medications.

Diana Jordan stated that VDH received an overall grant award of $24.6 million from Ryan White Part B, formerly Ryan White Title II. This is a 13% overall increase in funding. The ADAP earmark was $16.7 million, which is a 2.6% increase from the combined ADAP earmark and ADAP supplemental last year. The reauthorization affected the distribution of ADAP supplemental funds, and it is not known at this time whether Virginia will receive a supplemental grant award.

The reauthorization requires that 75% of the grant award go toward core medical services as defined in the legislation. One of the challenges is that the law states that services provided through the consortia are not counted as a core service, and count toward "supportive services". Virginia is fortunate. Planned ADAP spending, including some use of Part B base award funds, will account for the 75% core medical services. The question was asked by Dr. Oldfield if the 75% core service requirement is immediate and will VDH be taking on some of the consortia's activities. Diana Jordan responded that

the 75% of funds to core services is immediate and will be met by planned ADAP spending, and that the agenda for today's meeting includes discussing moving some medications currently purchased through consortia to ADAP. This will assist with meeting the requirement.

Diana Jordan said that there was a $75 million increase in congressional funding for Part B. However there were some major changes in requirements for all grantees. It is now a requirement that each state ADAP have a minimum ADAP formulary to include all classes of antiretrovirals. Virginia already meets this requirement. Another change is that states will need a special waiver to utilize carryover if that amounts exceeds 2% of the award. This may affect some Part A areas. Virginia has not historically exceeded this amount in carryover. Additionally, the Minority AIDS Initiative (MAI) is now competitive and will be on a different funding cycle. VDH will assist current MAI projects with Part B funds, and will compete for MAI when that guidance is issued.

Ms. Jordan noted that VDH has knowingly been out of compliance with the Health Resources and Services Administration's (HRSA) requirement that ADAP clients be recertified every 6 months. Local health departments have been effectively administering ADAP, but this frequency of recertification has not been feasible. VDH has always communicated this issue to HRSA, and there has been no penalty at this point. However, this recent increase in funding will allow VDH to examine ways to reach compliance with this requirement.

Faye Bates initiated the discussion of adding medications to the ADAP formulary. Currently, some clients receive assistance with medications through Part A and Part B funds, usually at retail rates. Because medications can be obtained through the VDH Central Pharmacy at reduced rates, it would be more cost-effective to add some of the more commonly prescribed medications to the ADAP formulary. Information was obtained from the Advisory Committee members in 2006 by email poll on the most commonly used diabetic agents, lipid controlling agents, and medications for neuropathy. The poll requested the percentage of clients seen that would need these agents. The results revealed that 20% of clients receiving antiretrovirals would be prescribed lipid controlling agents, 14% would be prescribed diabetic agents, and 10 % would be prescribed medication for neuropathy. The diabetic agents presented were glipizide, metformin, glyburide, and the combination agents glipizide/metformin and glyburide/metformin. The estimated cost of the diabetic agents to ADAP would be $32,534. In addition to the list provided, it was suggested that insulin be added to the formulary. The types of insulin, shipping costs, and storage issues will be investigated. The question of whether supplies would be covered was asked, and this will be investigated further. The committee recommended that the diabetic agents presented be added to the ADAP formulary. It was requested by the committee members that rosiglitazone maleate and pioglitazone hydrochloride be considered for future formulary consideration. Pricing and utilization information will be investigated.

The medication list for lipid reduction agents and neuropathy was discussed. The list consisted of atorvastatin, pravastatin, and gabapentin for neuropathy. Due to the

significant cost of atorvastatin, a question was raised if exception criteria should be considered. After much discussion, it was recommended that it would not be in the best interest of treatment to put additional exception criteria on this medication, but educate prescribers about the cost issue when prescribing. The committee recommended that atorvastatin, pravastatin, and gabapentin be added to the ADAP formulary. It was also requested by the committee that rosuvastatin calcium, and fish oil be considered for future formulary consideration. Pricing and utilization information will be investigated.

The next item on the agenda is exception criteria review for enfuvirtide, tipranavir, and darunavir. There was a question from one of the local health departments for consideration. The question is when an ADAP client has met exception criteria, is it necessary to complete the medication exception form every 3 months? The pharmaceutical company, Tibotec, expressed a concern that the existing exception criteria for darunavir was too restrictive.

It was decided by the committee that when a client has met the exception criteria for a particular medication, there is no need for the repeated exception paperwork every 3 months. These medications would require a one time exception approval, and then would be managed under existing ADAP policy for antiretroviral agents. Once a client is approved under exception criteria for one medication, that client is considered approved to access any medication under the same exception criteria. The medical criteria was reviewed by the committee, and as a the result of the discussion, the medical exception criteria for enfuvirtide, tipranavir, and darunavir will be changed to "NRTI and NNRTI experienced, with either a viral load greater than 400 or intolerance to current regimen, and prior experience with one or more PIs."

Kate Cooke, Incidence/Resistance Epi Consultant gave a presentation on HIV Incidence/Resistance Surveillance. The goal of the project is to provide national and area-specific, population-based estimates of the number of new infections per year to better target prevention and care efforts towards the segments of the population that show recent transmission.

Daniel Nixon DO, gave a presentation of the new antiretrovirals likely to be approved in the near future. The medications in the pipeline are raltegravir, an integrase inhibitor, maraviroc, a CCR5 entry inhibitor, and etravirine, a second generation NNRTI. Maraviroc works by blocking a protein called CCR5, on human immune system cells that HIV uses as a portal to enter and infect cells. The new entry inhibitor, maraviroc, will require a "tropism" test prior to treatment. Only individuals that have the CCR5 protein will benefit from the medication. The cost of the test is substantial at this time. The drug company, Pfizer, will be looking into providing some assistance in clients obtaining this test. Monogram Bioscience Laboratory developed this test. However, initial study data shows that the new drugs may not require ritonavir boosting, have a low resistance profile, and few side effects.

Anne Rhodes, Survey and Evaluation Research Laboratory, presented the ADAP Data Report. The total numbers served from February 2006 to March 2007 were 3343. For

the same time period of the previous year, 3541 clients were served. The number of active clients March 2007 was 2518. For March 2006, the number of active clients was 2965. The growth rate for ADAP was 5.2% for Ryan White Grant year 2005, but for 2006 it was -14.1%. This appears to be attributable to the implementation of Medicare Part D, and this trend is expected to level out. Increasing medication costs and client enrollment time periods support the continuing need for increased ADAP funding.

Items for the ADAP Advisory Committee agenda for the next meeting include information on treatment adherence and quality assurance standards on targeted interventions. There was discussion on the new CDC testing guidelines, and the impact on medical services and ADAP. The committee requested input from VDH regarding the new testing guidelines.

No date was set for the next meeting. The meeting was adjourned at 2:00 p.m.